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February 27, 2004

**OFFICIAL**

**TO: Examiner Borin (TC1600)**

**GROUP: 1631**

**FAX NUMBER: 703-872-9306**

**ATTORNEY DOCKET NO.: DEX-0312**

**SERIAL NO.: 10/078,090**

**FILED: February 14, 2002**

**NUMBER OF PAGES: 9**

**MESSAGE:** Attached please find Amendment Transmittal Letter, Reply to Restriction Requirement and Certificate of Transmission by Facsimile.

**Kathleen A. Tyrrell, Registration No. 38,350**

**URGENT! PLEASE DELIVER IMMEDIATELY UPON RECEIPT. THANK YOU!**

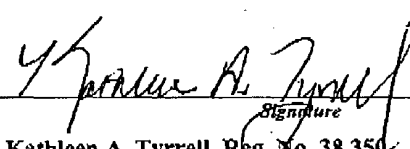
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<b>AMENDMENT TRANSMITTAL LETTER (Large Entity)</b>			Docket No. <b>DEX-0312</b>		
Applicant(s): <b>Salceda et al.</b>					
Serial No. <b>10/078,090</b>	Filing Date <b>February 14, 2002</b>	Examiner <b>Borin, Michael L.</b>	Group Art Unit <b>1631</b>		
Invention: <b>Compositions and Methods Relating to Breast Specific Genes and Proteins</b>					
<u>TO THE COMMISSIONER FOR PATENTS:</u>					
Transmitted herewith is an amendment in the above-identified application. The fee has been calculated and is transmitted as shown below.					
<b>CLAIMS AS AMENDED</b>					
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	19 -	20 =	0 x	\$18.00	\$0.00
INDEP. CLAIMS	2 -	3 =	0 x	\$86.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
<b>TOTAL ADDITIONAL FEE FOR THIS AMENDMENT</b>					<b>\$0.00</b>
 <input checked="" type="checkbox"/> No additional fee is required for amendment. <input type="checkbox"/> Please charge Deposit Account No. _____ in the amount of _____ <input type="checkbox"/> A check in the amount of _____ to cover the filing fee is enclosed. <input checked="" type="checkbox"/> The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. <b>50-1619</b> <input checked="" type="checkbox"/> Any additional filing fees required under 37 C.F.R. 1.16. <input checked="" type="checkbox"/> Any patent application processing fees under 37 CFR 1.17.					
 Kathleen A. Tyrrell, Reg. No. 38,350			Dated: <b>February 27, 2004</b>		
Licata & Tyrrell P.C. 66 East Main Street Marlton, New Jersey 08053 Tel : 856-810-1515 Fax: 856-810-1454			<div style="border: 1px solid black; padding: 5px;"><p>I certify that this document and fee is being deposited on _____ with the U.S. Postal Service as first class mail under 37C.F.R. 1.8 and is addressed to the for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p><hr/><p style="text-align: center;">Signature of Person Mailing Correspondence</p><hr/><p style="text-align: center;">Typed or Printed Name of Person Mailing Correspondence</p></div>		
CC:					

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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FEB 27 2004

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Attorney Docket No.: DEX-0312  
Inventors: Salceda et al.  
Serial No.: 10/078,090  
Filing Date: February 14, 2002  
Examiner: Borin, Michael L.  
Group Art Unit: 1631  
Title: Compositions and Methods Relating to  
Breast Specific Genes and Proteins

## Certificate of Facsimile Transmision

I hereby certify that this document is being facsimile  
transmitted to the Patent and Trademark Office on  
the date shown below.

On February 27, 2004

  
Kathleen A. Tyrrell, Registration No. 38,350

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Reply to Restriction Requirement

This is a reply to the Restriction Requirement mailed  
January 28, 2004 setting a one (1) month statutory period for  
response. Please enter the following remarks into the record.

Remarks begin at page 2.

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Inventors: Salceda et al.  
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REMARKS

Claims 1-17 are pending in the instant application. Claims 1-17 have been subjected to a Restriction Requirement as follows:

Group I, claims 1-5 and 7-9, drawn to isolated nucleic acid, expression vectors, cells comprising the vector, and method of producing a polypeptide classified in class 536, subclass 23.1 and class 935, subclass 66;

Group II, claim 6, drawn to method of use of product of Group I for detecting polynucleotide, classified in class 435, subclass 6;

Group III, claims 10, 11, drawn to a purified polypeptide encoded by a polynucleotide, classified in class 530, subclass 300;

Group IV, claim 12, drawn to an antibody to a polypeptide, classified in class 530, subclass 388.1;

Group V, claim 13, drawn to antibody-based methods of screening, classified in class 435, subclass 7.1;

Group VI, claim 14 (in part), drawn to peptide-based method of screening, classified in class 435, subclass 7.1;

Group VII, claim 14 (in part), drawn to polynucleotide-based method of screening, classified in class 435, subclass 6;

Group VIII, claim 15, drawn to diagnostic kit comprising

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means for determining products of Groups I or III;

Group IX, claim 16, drawn to use of antibody in cancer treatment;

Group X, claim 17 (in part) drawn to vaccine comprising polypeptide of Group I, classified in class 424, subclass 184.1; and

Group XI, claim 17 (in part) drawn to vaccine comprising polynucleotide of Group II, classified in class 424, subclass 184.1.

The Examiner suggests that the Groups are distinct. Specifically, with respect to Groups I and III, the Examiner suggests that the claims are directed to different chemical types regarding the critical limitations. With respect to Groups III and IV, the Examiner suggests that the claims are drawn to structurally and biochemically different polypeptides and antibodies, respectively.

With respect to Groups II and VII and Groups V and IX, the Examiner suggests that the claims are drawn to alternative methods of use of polynucleotides and antibodies, respectively.

With respect to Group VIII, the Examiner suggests that the claims kit is unrelated to the other Groups.

Finally, with respect to Groups II and X, Groups I and XI,

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and Groups X and XI, the Examiner suggests that the claims are drawn to patentably distinct products, respectively.

Further, at page 5 of the Restriction Requirement under the heading entitled "Sequence Election Requirement Applicable to Groups III-VIII", the Examiner suggests that each Group detailed above reads on a plurality of independent and/or patentably distinct sequences and has requested Applicants to elect a single amino acid or nucleic acid sequence. Clarification as to whether this sequence election requirement is applicable to all Groups or merely Groups III-VIII is respectfully requested.

Applicants respectfully traverse this Restriction Requirement.

MPEP §803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A search of prior art relating to an elected nucleic acid, polypeptide or antibody would also reveal any references teaching uses for the nucleic acid, polypeptide or antibody. Accordingly, Applicants believe that searching of all the claims, at least when limited to elected nucleic acids or polypeptides is overlapping and would not place an undue burden

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on the Examiner if the Restriction is not made.

Thus, since this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper, reconsideration and withdrawal of this Restriction Requirement is respectfully requested.

In addition, with respect to the election of a single sequence, MPEP § 803.04 clearly states that a reasonable number of nucleotide sequences, normally ten sequences, can be claimed in a single application. Accordingly, withdrawal of this sequence election requirement and reconsideration to include a more reasonable number of at least 10 sequences in accordance with MPEP § 803.04 is also respectfully requested.

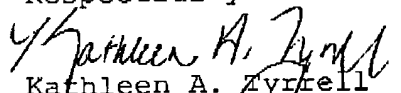
However, in an earnest effort to be completely responsive, Applicants elect to prosecute Group I, claims 1-5 and 7-9, with traverse. Clarification has been requested, *supra*, as to whether the sequence election is required for Group I. If a sequence election is required, Applicants elect SEQ ID NO:48 encoding SEQ ID NO:151, with traverse. Inclusion of SEQ ID NO:47 in the prosecution of this case is respectfully requested since it is a subsequence of SEQ ID NO:48.



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Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Reg. No. 38,350

Date: February 27, 2004

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